

REMARKS

This is a response to the final Office Action mailed on October 25, 2011. No fee is due in connection with this response. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-01345 on the account statement.

Claims 1-3, 8 and 10-14 are currently pending. Claims 4-7 and 9 were previously canceled without disclaimer. In the Office Action, Claims 1-3, 8 and 10-14 are rejected under 35 U.S.C. §103. For at least the reasons set forth below, Applicants respectfully traverse the rejection and submit that the rejection should be reconsidered and withdrawn.

In the Office Action, Claims 1-3, 8 and 10-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2001/0014322 to Chen ("*Chen*") in view of U.S. Patent No. 7,198,936 to Silfversparre et al. ("*Silfversparre*") and further in view of U.S. Patent No. 7,374,753 to Farmer et al. ("*Farmer*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claim 1 recites, in part, a method for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of a meat peptone and about 0.3% to about 7% by volume of a meat extract. Independent Claim 12 recites, in part, a method for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of a meat peptone and about 0.3% to about 7% by volume of a meat extract, and from 0.01 to 5% by volume of a yeast extract. As taught by Applicants' specification, the term "peptone" means any soluble mixture of products produced by the partial enzymatic or acid hydrolysis of proteinaceous material. In this regard, a meat peptone has a meat protein as the protein starting material. For example, a meat peptone is an enzymatic digest of animal tissue. As taught by Applicants' specification, the term "meat extract" is intended to cover extracts of any meat, such as beef, pork, lamb, chicken and/or turkey, among others. It may also be from a mixture of the above-cited meats. In any event, it can provide at least nitrogen, amino acids, and carbon.

Applicants have surprisingly found that by ingesting meat extracts together with meat peptones, individuals suffering from infection by pathogens as evidenced by intestinal disorders such as, for example, failure of gut epithelial integrity and diarrhea, have a normalized fluid secretion, a cellular structure less damaged, and a decreased inflammation compared to individuals having the same disorders, but a diet not supplemented with meat extracts or peptones. See, specification, page 5, lines 20-25, and Examples 1-2.

Applicants respectfully submit that the cited references alone or in combination fail to disclose or suggest each and every element of independent Claim 1. Specifically, *Chen*, *Silfversparre* and *Farmer* alone or in combination fail to disclose or suggest methods for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of a meat peptone and about 0.3% to about 7% by volume of a meat extract as required by independent Claims 1 and 12.

In contrast, *Chen* discloses a microbe composition comprising three viable and beneficial lactic acid producing bacteria of new strains: *Bifidobacterium bifidum* 6-1, *Lactobacillus acidophilus* YIT 2004 and *Streptococcus faecalis* YIT 0027. *Chen* also provides the materials to protect the viability of the lactic acid producing bacteria in lyophilized form and the method to prepare the composition. However, *Chen* fails to disclose the use of a meat peptone or the advantages of using same anywhere in his disclosure. In fact, the Patent Office expressly acknowledges that “*Chen* is silent towards meat peptones.” See, Office Action, page 3, line 5.

Silfversparre discloses methods for growth of bacteria such as Gram negative bacteria and its corresponding supernatant. *Silfversparre* is focused on cultivating bacteria without substantial formation of acetic acid and cultivation by controlling the level of carbon/energy source and limiting available oxygen. See, *Silfversparre*, Abstract. Although *Silfversparre* discloses examples of a growth medium that may contain soy meal, fish meal, yeast extract, and peptones of casein, soy, fish and meat, see, *Silfversparre*, Table 1, *Silfversparre* still fails to disclose or suggest oral compositions having a meat peptone and a meat extract, let alone administering to a human or animal an oral composition having a meat peptone and a meat extract, according to the present claims. Indeed, *Silfversparre* expressly states that the bacteria may be added to a growth medium, the growth may continue or a predetermined amount of time

to obtain a desired cell concentration, and then the cells are harvested from the growth medium. See, *Silfversparre*, column 5, line 15-column 6, line 30. It is well known in the art that harvesting cells from a growth medium means that the cells are removed from the growth medium and/or filtered from the growth medium. Accordingly, *Silfversparre* fails to disclose or suggest the preparation of any oral compositions including meat extracts and meat peptones, let alone administering such compositions to individuals in need of same.

Instead, it appears that the Patent Office has cited *Silfversparre* simply because of the mention of a growth medium that may include soy meal, fish meal, yeast extract, and peptones of casein, soy, fish and meat. Indeed, the Patent Office even admits that it uses *Silfversparre* for the disclosure of “soluble whey peptones of casein, soy, fish, and meat [] used in the medium to meet [the limitation of meat peptones].” See, Office Action, page 4, lines 13-17. The skilled artisan will appreciate, however, that a bacteria cultivating medium and an oral composition intended to be ingested by a consumer are two very different compositions intended for very different uses. In fact, *Silfversparre* fails to even consider the advantages of administering its growth medium to an individual, presumably because individuals typically do not ingest bacterial growth medium. Accordingly, it is clear that *Silfversparre* fails to disclose or suggest the preparation of any oral compositions including meat extracts and meat peptones, let alone administering such compositions to individuals in need of same.

Farmer discloses the use of compositions including a lactic acid bacteria for administration to the intestinal tract for inhibiting infections including Sudden Infant Death Syndrome (“SIDS”). See, *Farmer*, Abstract. At no place in the disclosure does *Farmer* consider the use of oral compositions having meat peptones and meat extracts, let alone compositions having meat peptones and meat extracts in the presently claimed volumetric amounts. Moreover, and similar to *Silfversparre*, because the peptone (no description of type) and meat extract of *Farmer* are only used as a culture medium to grow bacteria and never in a composition administered to a human or an animal (see, *Farmer*, Example 1), *Farmer* fails to disclose administering to a human or animal an oral composition having a meat peptone and a meat extract.

Also similar to *Silfversparre*, *Farmer* expressly states that bacteria is grown in a nutrient broth that may contain peptones and meat extract. *Farmer* also expressly states, however, that

after fermentation the bacterial cells are collected from the nutrient broth (e.g. filtration, centrifugation, etc.) and dried. See, e.g., *Farmer*, Examples 1 and 2. Again, Applicants respectfully submit that simply because *Farmer* mentions the use of a culture medium that may contain peptones and meat extracts, does not mean that *Farmer* discloses administering to a human or animal an oral composition having a meat peptone and a meat extract. Indeed, the culture medium of *Farmer* is discarded after growth of the bacterial cells.

For at least the reasons discussed above, the cited references fail to disclose or suggest each and every element of independent Claims 1 and 12. Moreover, the cited references fail to even recognize the advantages, unexpected benefits and/or properties of a method for treating the effects of infection by enterotoxin-producing pathogens in accordance with the present claims. As a result, Applicants respectfully submit that independent Claims 1 and 12, along with any claims that depend from Claims 1 and 12, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejection of Claims 1-3, 8 and 10-14 under 35 U.S.C. §103 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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